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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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2419'	7590	10/03/2003	EXAMINER	
KLARQUIST SPARKMAN, LLP			LUCAS, ZACHARIAH	
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SUITE 1600			PAPER NUMBER	
PORTLAND, OR 97204			1648	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,000

Applicant(s)

WONG ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-37, 44, 47-49, 52, and 59-62 is/are pending in the application.

4a) Of the above claim(s) 44 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 35-37, 47-49, 52 and 59-62 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The claims of Group I, claims 35-37, 47-49, 52, and 59-62 are pending and under consideration in the application.

The traversal is on the ground(s) that the elected invention, drawn to a virus, inherently includes the inventions of Group III, drawn to nucleic acids encoding individual viral proteins, and thus, there is no undue burden in searching each of the inventions of Group I and Group III. This is not found persuasive because, while the virus does comprise these nucleic acids, it does not rely on any one of them for patentability. Further, a search for a complete virus, and a complete viral sequence does not inherently include a search for each of the genes included in the virus. A search for each gene individually, rather than a complete viral genome, is required for the inventions of Group III, while no such search is required for Group I. Thus, the Applicant's argument in traversal is not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 44 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

It is noted that the Applicant appears to have intended to cancel all claims, including claim 44, in the Response to the Election Requirement. However, claim 44 was not indicated as

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cancelled in the claim listing submitted with the Response, although it was listed as cancelled on page 8 of the Response. Claim 44 is therefore being treated as pending and withdrawn.

Clarification of the status of this claim is requested in the Response to this action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on February 11, 2002, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 47 and 48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on non-human mammals, including primates, purposefully infected with the virus of claim 36. However, Searles et al. (J Virol 73: 3040-53, at 3040- of record in the IDS), teaches that the RRV isolate 17577 (the same virus currently claimed, page 16, lines 30-32), was originally isolated from an SIV infected Macaque. Thus, the reference teaches that the virus naturally infects primates, and therefore that primates infected with the virus are naturally occurring. See also, Derosiers et al., J Virol 71: 9764-69 (of record in the IDS). It is noted that the present claims are directed to primates purposefully infected with the virus. However, there is no structural distinction between such primates, and

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primates that become infected by the virus in the wild. Thus, the claims are directed to products not made by the hand of man, and therefore read on non-statutory subject matter.

6. Claims 59-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on a method of producing a non-human primate model for testing potential treatments for RRV infection comprising administering to the primate a treatment to render the primate immunocompromised (e.g. through administration with SIV), and infecting the primate with RRV. However, in the Searles reference, it was disclosed that the claimed RRV virus was originally isolated from an SIV infected rhesus macaque. Page 3040, last paragraph. Thus, the steps of the claimed method (infection by SIV, and infection with RRV) are steps that occur in nature. Because the steps of the claimed method occur in nature, the claims read on non-statutory subject matter.

Claim Objections

7. Claim 35 is objected to because of the following informalities: The claim reads on an "isolated virus (RRV)..." The claim refers to RRV by its acronym without first identifying the virus by its complete name (Rhesus rhadinovirus). Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim describes an isolated nucleic acid encoding all of the proteins of an RRV, and having a biological activity of such. However, the Applicant has not identified any biological activities of the virus as whole other than the ability to infect an animal. Nor has the Applicant has not shown that the DNA alone has the ability to infect an animal. Thus, it is unclear what is meant by the phrase "having a biological activity of an RRV virus).

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 35-37, 47, 48, 52, and 59-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **Deposit without a promise for availability-** The virus of ATCC deposit VR-2601 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the claimed/described virus. See 37 CFR 1.802.

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The specification does not provide a repeatable method for obtaining the virus and it is not apparent if it is readily available to the public. Applicant's deposit statement on specification page 16 does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Absent such a statement, the claims are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

12. Claims 36, 37, 47-48, and 59-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for viruses, and methods of using viruses, comprising the genome of SEQ ID NO: 1, does not reasonably provide enablement for the claimed inventions wherein the virus comprises variants, even conservative variants, of the virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims read on products comprising, and methods of using, viruses with the nucleic acid sequence of SEQ ID NO: 1, or conservative variants thereof. It is assumed, as per the language on page 24, lines 27-33, that a conservative variant of the nucleic acid of SEQ ID NO:

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1 refers to a nucleic acid sequence encoding a one or more proteins with a conservative variations as compared to the proteins encoded by SEQ ID NO: 1.

The specification provides the genomic sequence of the RRV of ATCC VR-2601. See, page 36, lines 28-30 (indicating that SEQ ID NO: 1 is the genomic sequence of the RRV of ATCC VR-2601). The specification further identifies the ORFs, and the protein sequences encoded thereby, of the viral genome. However, while the specification does identify homologous proteins in other virus for some of the identified RRV proteins, the Applicant has not provided examples of conservative variants for any of the proteins, nor identified any residues essential for the protein functions. There is little guidance in the application that would allow one skilled in the art to determine the effect of a particular conservative substitution on the function and structure of the encoded proteins.

13. It is known in the art that a change in a protein sequence, even a conservative substitution, can effect great changes on the operability and function of the variant protein. See e.g., Bowie et al., Science 247: 1306-10. Bowie teaches that, while proteins are tolerant to substitutions, the effect of a substitution of any particular residue is dependent on the importance of the affected amino acid to the proteins structure/function. Page 1306. It is noted that, in the present case the Applicant has indicated that several proteins encoded by the claimed RRV genome have known homologues in other viruses. However, the Applicant has not provided sufficient information as to which residues in the RRV proteins are required to maintain or reduce the operability of the those proteins. Because the Applicant has not provided sufficient guidance to those in the art that they could make operable conservative variants of the claimed

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sequence, the Applicant is not enabled for the claimed viruses to the extent that the claims cover virus with other than the nucleic acid of SEQ ID NO: 1.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 35-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Searles et al. (J Virol 73: 3040-53). These claims read on isolated RRV comprising the genome of SEQ ID NO:

1. The present application teaches that the presently claims virus is of the isolate 17577, as is the virus of the Searles reference. As the prior art reference appears to be teaching the isolation of the same virus as is presently being claimed, and as the reference identifies authors not identified as inventors of the present application, the reference is a prior teaching by another of the claimed subject matter. The reference therefore anticipates the rejected claims.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 49 is rejected under 35 U.S.C. 103(a) as obvious over Mahairas et al. (Genbank Accession number AQ622034). Claim 47 describes oligonucleotides comprising a sequence of at least 30, at least 30, or at least 50 consecutive bases of SEQ ID NO: 1. The oligonucleotide disclosed by Mahairas comprises, at positions 275-296, a sequence that is identical to 22 bases of the sequence of SEQ ID NO: 1 (at positions 63334-63355). It would have been obvious to those in the art to make oligomers of the Mahairas sequence. Because the sequence comprises a sequence of 20 bases that is identical to a section of SEQ ID NO: 1, and because it would have been obvious to make any oligomer of this sequence, it would also have been obvious to make an oligomer comprising the 22 bases identified above.

18. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Derosiers et al., Genbank Accession AF029302 (discussed in Derosiers et al., J Virol 71(12), of record in the IDS); Berthomme et al., Accession L24487 (discussed in Berthomme et al., J Virol 69: 2811-18), Accession AF087411 (discussed in Wong et al., J Exp Med 190: 827-40, p. 829), or Davison et al. (J Gen Virol 67: 1759-1816). The claim has been described above.

The polynucleotide of AF029302 comprises a sequence that shares at least 50 polynucleotides of SEQ ID NO: 1. Compare, SEQ ID NO: 1, bases 19921-20040, with AF029302 bases 8711-9011.

The polynucleotide of Accession L24487 comprises a sequence that shares at least 30 polynucleotides of SEQ ID NO: 1. Compare, SEQ ID NO: 1, bases 15886-15931, with L24487 bases 1720-1765.

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The polynucleotide of Accession AF087411 comprises a sequence that shares at least 50 polynucleotides of SEQ ID NO: 1. Compare, SEQ ID NO: 1, bases 19403-23206, with AF087411 bases 1-3804.

The DNA disclosed in Davison comprises sequences with at least 20 identical nucleotides to those of SEQ ID NO: 1. Compare, Davison, page 1794, bases 96832-96852, with SEQ ID NO: 1, bases 711-31.

It would have been obvious to those in the art to make oligomers of at least 20, 30, or 50 bases of any of the identified sequences as probes, primers, etc. Because it would have been obvious to make oligomers of any set of bases in the disclosed sequences, it would have been obvious to make oligomers that include sequences including the identified bases identical to sequences within SEQ ID NO: 1. Thus, the teachings of these references, in combination with the knowledge of those within the art, render the products of claim 47 obvious.

Conclusion

19. No claims are allowed.
20. The following prior art reference is made of record and is considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.


Kaleeba et al., J Virol, 73: 6177-81 (of record in the IDS). This reference teaches the cloning of an RRV sequence encoding for the viral homologue of the IL-6 protein. However, the reference does not teach the sequence of the isolated polynucleotide. Because the sequence of the DNA is not disclosed, the reference is not used as a reference to rejection claim 52 for obviousness.

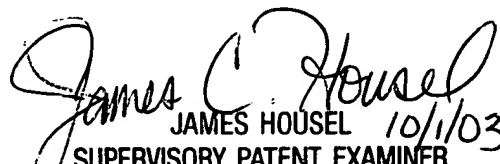
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21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner


JAMES HOUSEL 10/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600